K001398

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corgenix

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit
May 2, 2000

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is REAADS IgM anti-Beta 2 Glycoprotein I (K982391) currently manufactured and marketed by Corgenix, Inc., Wesminster, Colorado.

The REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA), utilizing the 96-microwell plate format, similar to the predicate device. Diluted serum samples, calibrator sera, and controls are incubated in microwells coated with purified human prothrombin. Incubation allows the anti-prothrombin antibodies present in the samples to react with the immobilized antigen. After the removal of unbound serum proteins by washing, antibodies specific for human IgM, labeled with horseradish peroxidase (HRP), are added forming complexes with the prothrombin bound antibodies. Following another washing step, the bound enzyme-antibody conjugate is assayed by the addition of a single solution containing tetramethlybenzidine (TMB) and hydrogen peroxide (H_2O_2) as the chromogenic substrate. The intensity of the color generated is proportional to the serum concentration of anti-prothrombin antibodies. Optical density is read spectrophotometrically at 450nm. The total incubation time (at room temperature) of the assay is 40 minutes. The assay makes use of a single point calibrator to measure the amount of IgM anti-prothrombin antibodies in patient samples.

The intended use of the device is for the detection and semi-quantitation of IgM anti-prothrombin (aPT) antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (e.g., antiphospholipid syndrome). Several plasma proteins have been identified as antiphospholipid cofactors. Beta 2 Glycoprotein I and prothrombin are the most common and extensively studied cofactors. Antibodies to prothrombin have been reported in patients with antiphospolipid syndrome (APS) and are proposed to be included in the serologic evaluation of antiphospholipid antibodies. Elevated levels of these antibodies are associated with an increased risk for APS, characterized by recurrent thrombosis, thrombocytopenia and/or fetal loss.

Performance indicates that REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit and the REAADS IgM anti-Beta 2 Glycoprotein I ELISA are equivalent. In-house studies indicate a clinical specificity of 97.5% and 97% for IgM Anti-Prothrombin antibodies in serum and plasma, respectively. Studies indicate a sensitivity of 12.2% for unselected SLE patients and 24.6% for lupus anticoagulant patients for IgM Anti-Prothrombin antibodies. In-house studies indicate a clinical sensitivity of 100% and 99% for IgM B2GPI antibodies in serum and plasma, respectively. Studies indicate a sensitivity of 12.5% for unselected SLE patients and 21.3% for lupus anticoagulant patients for IgM B2GPI antibodies. Although differences between the assays are observed, in general, the performance characteristics are comparable. These results are also in compliance with those in published literature for antiphospholipid syndrome detection. The clinical studies performed demonstrate that the REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit is safe and effective.

Nanci Dexter — 05/02/00

Nanci Dexter
Director, Quality Assurance and Regulatory Affairs

Date

12061 TEJON STREET • WESTMINSTER, CO • 80234 U.S.A.
PHONE: 303.457.4345 FAX: 303.457.4519 www.corgenix.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Nanci Dexter
Director, Quality Assurance and Regulatory Affairs
Corgenix, Inc.
12061 Tejon Street
Westminister, CO 80234

Re: K001398
Trade Name: REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit
Regulatory Class: II
Product Code: DHC
Dated: February 6, 2001
Received: February 8, 2001

Dear Ms. Dexter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K001398

Device Name: REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit

Indications for Use:

The REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit is an in vitro diagnostic assay for the detection and semi-quantitation of IgM anti-prothrombin (aPT) antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome).

The REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joseph J. Hackett